Remarks

Claims 1-2, 5-8 and 14-17 are amended. Claims 1-10 and 12-17 are pending in this application. The language of the claims has been amended to reflect the election made in response to the restriction requirement. Proper antecedent basis has also been provided in claims 5-8 for the nucleic acid-based vaccine delivered by an attenuated recombinant virus. Applicant submits that these amendments add no new matter.

Objection to the Claims

The Examiner objected to claims 1-10 and 12-17 stating that the claims should be amended to reflect the restriction requirement and election. Applicant respectfully submits that the amendments to claim 1 renders the objection to the claim moot. Therefore, Applicant respectfully requests withdrawal of the objection.

35 U.S.C. § 112, Second Paragraph, Rejection

Claims 1-10 and 12-17 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Specifically, the Examiner alleges that the phrase "efficient CD8+ response" is vague and indefinite as the claim allegedly fails to set forth the specificity and avidity of the CD8+ response, allegedly fails to identify which populations of CD8+ cells are being "activated" by the claimed methodology (CTL memory, effector, or precursor cells) and allegedly fails to specify suitable administration parameters such as target tissue (oral, mucosal, muscular), formulation, and vaccination regimes that lead to the desired response. The Examiner also alleges that reference to administration of a recombinant virus in claims 5-8 is indefinite because a nucleic acid-based vaccine is being administered.

Applicant submits that indefiniteness depends on whether one of skill in the art would understand the scope of the claim when the claim is read in light of the specification. *North American Vaccine Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 28 USPQ2d 1333 (Fed. Cir. 1993). If the claims read in light of the specification reasonably apprise those skilled in the art

of the scope of the invention, § 112 demands no more. *Miles Laboratories Inc. v. Shandon, Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993).

Claim 1 is directed to a method of stimulating an efficient $CD8^+$ response in a human infected with a HIV retrovirus said method comprising: administering to the human, a nucleic acid-based vaccine, which enters the cells of the human and intracellularly produces HIV-specific peptides for presentation on the cell's MHC class I molecules, where said peptides are presented in an amount sufficient to stimulate a protective $CD8^+$ HIV structural antigen response, and where said human (i) has a viral load of less than 10,000 viral copies per ml of plasma and a $CD4^+$ cell count of above 500 cells/ml, and (ii) has been treated with one or more anti-viral agents, which contributed to a lower viral copy and higher $CD4^+$ cell count than before treatment.

As prescribed by law, the claims are not interpreted in a vacuum. Instead, the claims are read in light of the specification. *North American Vaccine*, 7 F.3d 1571, 28 USPQ2d 1333. Thus, as described in the specification at page 4, lines 7-9, "an efficient $CD8^+$ response" is the ability of cytotoxic $CD8^+$ T cells to recognize and kill cells expressing foreign peptides in the context of a major histocompatibility complex (MHC) class I molecule. The scope of the claims is therefore definite in that it embraces stimulating cytotoxic $CD8^+$ T cells to recognize and kill cells that express foreign peptides in the context of a MHC class I molecule. No particular range of specificity or avidity for the CD8+ response is required so long as the desired effect (recognizing and killing cells that express foreign peptides) is achieved. Applicant submits that one of skill in the art can readily understand the metes and bounds of such a response because all that is required for observing such "an efficient $CD8^+$ response" is a simple test for, and observation of, dead cells that express foreign peptide in the context of a MHC class I molecule. Such tests are further described in the specification at page 14, line 22 to page 15, line 9, and other test are readily available in the art. Hence, the meaning of "an efficient $CD8^+$ response" is definite and no further phrase specifying the specificity and avidity of the response is needed.

Moreover, the populations of CD8+ cells are described by the specification at page 4, lines 7-9, as being cytotoxic $CD8^+$ T cells that recognize and kill cells that express foreign peptides. Hence, the activated cell type is definite.

The specification further describes suitable administration parameters such as target tissue (oral, mucosal, muscular), formulation, and vaccination regimes that lead to the desired response, for example, a page 10, line 25 to page 11, line 4; at page 15, line 11 to page 18, line 9; and in the Examples. No ambiguity therefore exists in the term "administering."

Applicant submits that the language of claim 1 is therefore definite and requests withdrawal of the indefiniteness rejection as it applies to claim 1 and claims that depend therefrom.

Moreover, the language of claims 5-8 is also definite, particularly in view of the insertion of clarifying language that defines the nucleic acid-based vaccine as being delivered by an attenuated recombinant virus. At page 4, lines 16-18, of the instant specification, "nucleic acid-based vaccines" is defined to "include both naked DNA and vectored DNA (within a viral capsid) where the nucleic acid encodes B-cell and T-cell epitopes and provides an immunoprotective response in the person being vaccinated." Thus, the claimed methods include not only direct DNA delivery vaccines, but also, viral vector delivery vaccines, such as recombinant viruses (claims 5-8; see, for example, page 5, lines 33 and page 6, line 9 through 11, line 4 of the instant specification) and attenuated recombinant viruses (see, for example, page 7, line 1 through page 9, line 22) comprising DNA encoding an antigenic sequence. Thus, reference to the administration of a recombinant virus in the context of the claims of the present invention would be readily recognized and understood by an art worker as a method of administering a nucleic acid-based vaccine.

It is respectfully submitted that the pending claims are in conformance with 35 USC 112, second paragraph. Therefore, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. 112, second paragraph, rejection of the claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21st day of September, 2004.

Dawn M. Poole

Name

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Signature